Title: Clinical practice guidelines for nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A modified Delphi study

Authors:
Aaron CONWAY RN, BN (Hons), PhD[1,2,3]
John ROLLEY RN, PhD[4]
Karen PAGE RN, DN[5]
Paul FULBROOK RN, PhD[3,6]

Affilliations:

1 School of Nursing & Institute of Health and Biomedical Innovation, Queensland University of Technology, Level 7 60 Musk Ave, Kelvin Grove QLD 4059.

2 The Wesley Hospital, Chasely St, Auchenflower, 4066. Cardiac Catheter Theatres.

3 Australian Catholic University, 1100 Nudgee Rd, Banyo QLD 4014. School of Nursing, Midwifery & Paramedicine (QLD).

4 Deakin University, Geelong Waterfront Campus, Locked Bag 20000, Geelong, VIC 3220. School of Nursing and Midwifery.

5 Heart Foundation, Level 12, 500 Collins St, Melbourne VIC 3000.

6 The Prince Charles Hospital, Level Seven Clinical Sciences Building, Rode Rd Chermiside, 4032. Nursing Research and Practice Development Unit.

Corresponding Author:
Aaron Conway
Institute of Health & Biomedical Innovation
QUT
Level 7 60 Musk Ave
Kelvin Grove QLD 4059

Tel. (07)3138 6124

Email: Aaron.conway@qut.edu.au

Acknowledgements

Aaron Conway received an Australian Postgraduate Award Scholarship (Federal Government Funding).

No conflict of interest has been declared by the authors

Abstract

Aim

To develop clinical practice guidelines for nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory.

Background

Numerous studies have reported that nurse-administered procedural sedation and analgesia is safe. However, the broad scope of existing guidelines for the administration and monitoring of patients who receive sedation during medical procedures without an anaesthetist presents means there is a lack of specific guidance regarding optimal nursing practices for the unique circumstances in which nurse-administered procedural sedation and analgesia is used in the cardiac catheterisation laboratory.

Methods

A sequential mixed methods design was utilised. Initial recommendations were produced from three studies conducted by the authors: an integrative review; a qualitative study; and a cross-sectional survey. The recommendations were revised in accordance with responses from a modified Delphi study. The first Delphi round was completed by nine senior cardiac catheterisation laboratory nurses. All but one of the draft recommendations met the pre-determined cut-off point for inclusion. There were a total of 59 responses to the second round. Consensus was reached on

all recommendations.

Implications for nursing

The guidelines that were derived from the Delphi study offer twenty four recommendations within six domains of nursing practice: Pre-procedural assessment; Pre-procedural patient and family education; Pre-procedural patient comfort; Intra-procedural patient comfort; Intra-procedural patient assessment and monitoring; and Post-procedural patient assessment and monitoring.

Conclusion

These guidelines provide an important foundation towards the delivery of safe, consistent and evidence-based nursing care for the many patients who receive sedation in the cardiac catheterisation laboratory setting.

Summary Statement

Why is this research needed?

- Nurses in the cardiac catheterisation laboratory are required to administer and monitor procedural sedation and analgesia in complex circumstances, often without an anaesthetist present.
- Nurses' decisions regarding the management of sedated patients have an impact on clinical outcomes. It is therefore important they have access to professional guidelines to support their clinical practice and decision-making.
- Clinical practice guidelines for procedural sedation and analgesia administered by nurses in the cardiac catheterisation laboratory setting will help to translate best evidence into practice.

What are the key findings?

- Recommendations for nursing practices associated with the administration and monitoring of procedural sedation and analgesia in the cardiac catheterisation laboratory setting are presented, together with a summary of the evidence to support these recommendations.

- A total of 24 recommendations for nursing practice, spanning pre, intra and post-procedural periods, were produced.
- There is a paucity of high-level evidence to inform nurses' clinical decision-making in this field.

How should the findings be used to influence policy/practice/research/education?

- These guidelines should be used to inform local hospital policy in support of nurse-administered procedural sedation and analgesia practice cardiac catheterisation laboratories.
- These guidelines should be used as a foundation for professional bodies to set standards for practice, competency, education and training.
- Further research should be conducted to strengthen justification for the recommendations derived from consensus and low-level evidence.

Keywords

Conscious sedation, Deep sedation, Heart catheterization, Artificial cardiac pacing, Cardiac electrophysiology, Nursing, Guidelines, Evidence-based practice.

Introduction

In the absence of an anaesthetist, nurses usually take responsibility for the administration and monitoring of PSA in the CCL (Conway et al. 2013b, Conway et al. 2012). Minimal, moderate or deep sedation may be used according to procedural requirements, cardiologists' preferences and patient characteristics including their co-morbidities, level of pain and anxiety, and their sensitivity to sedative medications (Kezerashvili et al. 2008, Natale et al. 1996). Numerous studies have reported that nurse-administered procedural sedation and analgesia (PSA) is safe in the cardiac catheterisation laboratory (CCL) setting. Our recent integrative review of nurse-administered PSA in the CCL found that the authors of each included study reported this practice was safe due to the low incidence of reversible cardiopulmonary complications, which ranged from 2.4-9.4% (Conway et al. 2011). Of note, in the largest individual study conducted to date, only five deaths were observed in the roughly 10,000 patients studied (0.05%) (Kezerashvili et al. 2008). Importantly, the authors of this study reported that it was unclear whether the deaths were related to the administration of sedation (Kezerashvili et al. 2008).

As a result of the safety data that have been reported, this practice is now common around the world, including in Australia and New Zealand (Gaitan et al. 2011, Trentman et al. 2009, ANZCA 2010, Conway et al. 2013c, Conway et al. 2013b, Conway et al. 2012). Morevover, it is anticipated that nurse-administered PSA practice in the CCL will not only continue but will likely even expand in scope as more

minimally invasive procedures become available with the rapid advances in technology that characterises contemporary cardiology practice.

It is important to note, though, that nurses' decisions and actions regarding the management of sedated patients have an impact on clinical outcomes (Odom-Forren 2005). For example, unrecognised sedation-induced hypoventilation can lead to hypoxic episodes (Burton et al. 2006, Conway et al. 2013a). Thus, it is important nurses have access to evidence-based and professionally endorsed guidelines to assist their clinical decision-making.

Anaesthetic professional organizations, such as the American Society of Anesthesiology and the Australian and New Zealand College of Anaesthestists, have produced guidelines to assist implementation of institutional policies and procedures for PSA that is administered without an anaesthetist present. In Australia and New Zealand specifically, the Australia and New Zealand College of Anaesthetists' guidelines provide recommendations for the type of patients and the sedative and analgesic medications that are suitable, as well as training standards for non-anaesthetist medical practitioners, staffing and patient monitoring requirements for PSA (ANZCA 2010). While these guidelines have been developed using robust methods and are informed by experts' opinions, unfortunately, their broad scope has resulted in a lack of specific guidance regarding optimal nursing practices for the unique circumstances in which nurse-administered PSA is currently being used in the CCL. For example, while guidelines developed by the anaesthetics professional organisation recommend that an anaesthetist should be present if deep sedation is

to be used, in many CCLs around the world, deep sedation is administered by nurses (Conway et al. 2013c, Gaitan et al. 2011).

Due to the non-specific nature of current guidelines, this study was designed to supplement existing guidelines by developing evidence-based recommendations for the unique circumstances in which nurse-administered PSA is currently being used in the CCL. Moreover, by producing an easy-to-use reference of the evidence-base supporting the recommendations, the guidelines aim to help nurses to make informed choices when caring for patients who are sedated in the CCL. The recommendations for nursing practice presented in this article have been endorsed by the Australia and New Zealand Interventional Nurses' Council.

Methods

This study was informed by the National Health and Medical Research Council principles for the development of clinical practice guidelines (NHMRC 1998). A sequential mixed methods design (Creswell and Plano Clark 2007), comprising two phases, was used to develop guidelines for nurse-administered PSA in the CCL. Figure 1 illustrates the process used.

The aims of Phase One were: 1) to appraise the current evidence available to inform nursing practices associated with the administration and monitoring of patients who receive PSA in the CCL setting; 2) to explore CCL nurses' perceptions of the issues and challenges associated with nurse-administered PSA in the CCL; and 3) to characterise current nurse-administered PSA practices across Australian and New

Zealand CCLs. Phase One commenced with an integrative review of research regarding nurse-administered PSA in the CCL and other clinical areas, including review of relevant clinical practice guidelines (Conway et al. 2011). This was the first review to systematically appraise the available evidence supporting the use of nurse-administered PSA in the CCL. A major finding was that, overall, nurse-administered PSA in the CCL was generally deemed to be safe. However, it was concluded from the analysis of the studies that were included in the review, that the management of sedation in the CCL was impacted by a variety of contextual factors including local hospital policy, workforce constraints and cardiologists' preferences for the type of sedation used.

The second study in Phase One was a qualitative study. Its aim was to explore the issues and challenges associated with nurse-administered PSA in the CCL. A total of 23 nurses from 16 CCLs across four Australian states and New Zealand participated in the study. While the results of the qualitative study are reported elsewhere (Conway et al. 2013b), in brief, major themes emerged from analysis of the qualitative data regarding the lack of access to anaesthetists, the limitations of sedative medications, the barriers to effective patient monitoring and the impact that the increasing complexity of procedures has on patients' sedation requirements.

The final component of the Phase One was a practice survey, which was conducted to characterise current nurse-administered PSA practice in Australian and New Zealand CCLs (Conway et al. 2013c). Of the estimated total number of CCLs in Australia and New Zealand, 54% responded to the survey. While nurse-administered PSA was reported to be used in nearly all the CCLs surveyed (n = 58; 94%), sedation-

monitoring practices varied considerably between institutions. The most common medications used for nurse-administered PSA were benzodiazepines, opioids or a combination of both. Deep sedation was purposefully induced during nurse-administered PSA in 20% (n = 12) of respondents practice settings.

Based on the findings from the exploratory phase, a draft set of guideline recommendations was developed by the research team. This paper presents results of the final phase, consisting of a modified Delphi study, which was conducted to refine the draft set of guidelines by consensus of practicing CCL nurses' opinions.

Design

A modified Delphi study was conducted. The Delphi technique is recognised as a valid and reliable method to achieve consensus (Powell 2003). As participants were asked for their reactions regarding previously prepared information derived from Phase One of this project, the particular 'modification' of the Delphi technique used in this study is known as 'reactive' (McKenna 1994). Ethical approval was received from a university human research ethics committee (HREC Register Number V2011 46). All data were collected anonymously. Participation was voluntary and participants were free to withdraw from the study at any time.

Procedure

As is recommended for a Delphi study, an expert panel was recruited for the first round (Hasson et al. 2000). An invitation to participate in the expert panel was sent by email to known contacts from the chair of the Australia and New Zealand Interventional Nurses' Council. The inclusion criteria were that participants were

currently employed within the CCL setting in a senior clinical role or with clinical experience in the CCL setting of three or more years and had an interest in PSA in the CCL. Nine nurses agreed to participate in the panel. Two participants practised in New South Wales, two in South Australia, three in Western Australia and two in New Zealand. This was considered to be an adequate panel size as previous research has indicated that views of a small group with expert knowledge can be representative of a target population (Vella et al. 2000).

In round one, a survey was distributed to the expert panel, which consisted of six items for each of the recommendations as well as free text space for suggestions about wording, content and missing recommendations (see Table 1). The items requested panel members to rate their agreement on a 10-point scale. A 10 point scale with descriptors at each end was chosen for this study because these types of scales have demonstrated acceptable validity and reliability (Pettersen et al. 2004). A hierarchy, which was used in a previous cardiovascular nursing clinical practice guideline development process, was used to grade each recommendation (Rolley et al. 2011). Practices supported by high-level research evidence were accorded the strongest recommendation, while those without research evidence were graded according to the level of consensus reached (see Table 2). Recommendations in the draft of the guidelines were refined through descriptive analysis of the survey data. Twenty seven recommendations were submitted to the expert panel for evaluation in round one. Only one of the recommendations scored below the median cut-off score of 7.5 to indicate consensus. For this reason, the recommendation was excluded from the revised set of guidelines. This recommendation related to the

need for research into medications other than midazolam and fentanyl for nurse-administered PSA in the CCL (median = 7; IQR = 2). In light of suggestions from the consensus panel, two further recommendations were removed by combining their content with two related recommendations and minor changes were made to the wording of other recommendations in order to increase clarity. Thus, there were 24 recommendations in the revised set of guidelines that were sent for consideration by the consensus panel in round two.

Following development of a revised set of guidelines, a broader sample of CCL nurses (consensus panel) was sought to determine the degree of consensus on the recommendations. Only small improvements in reliability were expected from recruiting a larger sample size for the second round of the Delphi study (Ayanian et al. 1998). Yet, it was highly relevant in this study to try to maximise the potential for the guidelines to be representative of the views of practising CCL nurses because, due to limited research evidence, many of the recommendations needed to be made by consensus rather than from patient outcome data. An invitation to participate in a consensus panel was sent by email to known contacts of the chairperson of the Australia and New Zealand Interventional Nurses' Council. In addition, a snowball sampling method was utilised in order to increase the number of participants (Wright and Stein 2005). The inclusion criteria were that participating nurses were currently registered and practising in a CCL. Fifty nine nurses agreed to participate. In this round, a survey similar to that used in round one, containing 24 recommendations, was distributed to the consensus panel. Again, a 10-point scale was used to rate agreement. A 100% response-rate (n = 59) was achieved in round

two. Over half of the consensus panel (54%) were Registered Nurses employed in senior CCL positions such as Clinical Nurse, Clinical Nurse Specialist, Clinical Coach, Nurse Co-ordinator or Nurse Manager. Participants were from South Australia (n=13, 22%), Western Australia (n=13, 22%), Queensland (n=10, 17%), Victoria (n=11, 19%), New South Wales (n=1, 2%), Tasmania (n=2, 3%) and New Zealand (n=9, 15%). All 24 of the recommendations reached the pre-determined cut-off point for consensus (median > 7.5).

Implications for nursing practice

The final recommendations for nursing practice, presented in Table 3, were categorised into six domains including pre-procedural assessment, pre-procedural patient and family and education, pre-procedural patient comfort, intra-procedural patient comfort, intra-procedural patient monitoring and post-procedural patient monitoring.

Domain 1: Pre-procedural assessment

Suitability for nurse-administered PSA

Some medical conditions have been shown to increase the risk of PSA-related complications (Taylor et al. 2011, Qadeer et al. 2009). Therefore, appropriate patient selection is vital for ensuring a safe PSA encounter. Moreover, it was noted by participants in phase one that it was important for processes to be in place to ensure that patients who may not be suitable for nurse-administered PSA are identified at a time that will ensure the procedure does not have to be delayed in order to arrange

anaesthetic support. As such, it is recommended that the cardiologist should be alerted and the suitability of nurse-administered PSA considered if patients exhibit risk factors for increased risk of PSA-related complications.

Recovery

In the qualitative study, it was identified that nurses perceived patients who received large doses of sedative and analgesic medications during long electrophysiology-based procedures required longer periods of close observation in the recovery area (Conway et al. 2013b). This finding is not supported by patient outcome data. As such, further research is required. Nonetheless, it is recommended by consensus that, in order to ensure adequate staffing is available, the potential for extended duration of sedation recovery should be considered.

Risk of complications

Recent evidence indicates that patient with acute illness are more likely to experience impaired respiratory function during nurse-administered PSA (Conway et al. 2013a). Also, the induction of deep sedation is associated with higher rates of PSA-related respiratory complications compared with moderate sedation (Conway et al. 2011). Therefore, it is recommended that risk of impaired respiratory function should be considered so that intensive respiratory monitoring, such as the use of capnography, can be selectively applied.

Risk of increased pain and discomfort

High levels of pre-procedural anxiety and pre-existing musculoskeletal injuries contribute to increased pain and discomfort during procedures (Beddoes et al. 2008, Gallagher et al. 2010). Therefore, consideration of these conditions is recommended to be part of pre-procedural assessment.

Domain 2: Pre-procedural patient and family education

Previous guidelines have recommended that patients should be provided with information about the risks of sedation and preparation requirements (Gross et al. 2002, ANZCA 2010). However, a major challenge associated with nurse-administered PSA in the CCL that was noted by nurses in the qualitative study, was the difficulty in managing patients who experienced a greater degree of pain or discomfort than they anticipated (Conway et al. 2013b). Therefore, it was recommended by consensus that information about the anticipated degree of pain and discomfort during the procedure should also be provided. Integrating this patient education into existing pre-procedural information that is already routinely provided would be the most optimal method of delivering this education (Astley et al. 2008).

Domain 3: Pre-procedural patient comfort

In the most recent and largest randomised controlled trial, patients who received premedication for cardiac catheterisation were not, as anticipated, less anxious than the control group (Woodhead et al. 2007). As there is limited evidence for administration of oral benzodiazepines to reduce anxiety, it is recommended pre-

medication is used on a patient-specific basis only.

Domain 4: Intra-procedural patient comfort

Medications for PSA

Serious adverse events associated with the administration of midazolam and fentanyl for nurse-administered PSA in the CCL are rare (Kezerashvili et al. 2008). As such, a combination of midazolam and fentanyl is recommended to be used for nurse-administered PSA in the CCL. It is important to note though, that other sedative and analgesic agents, such as propofol, dexmedetomidine, ketamine, and remifentanil have several desirable properties including a rapid onset of action and short half-life (Hayman et al. 2012, Behan et al. 2008, Mandel et al. 2011). Also, evidence demonstrating their safety is emerging (Kottkamp et al. 2011, Sayfo et al. 2012, Salukhe et al. 2012, Tang et al. 2007, Wutzler et al. 2012). However, more evidence is required in order to explicate the type of patients that are suitable, the degree of patient monitoring that is required and specific education, training and accreditation requirements (de Bono 2012, Hummel and Awad 2011). Therefore, the use of these agents for nurse-administered sedation in the CCL is not recommended for clinical practice.

Non-pharmacological stress reducing therapies

Investigations into the use of non-pharmacological stress reducing therapies, such as music therapy and visualisation, have found these interventions were simple to apply in practice, did not disrupt procedures and induced relaxation during cardiac

procedures (Nilsson et al. 2009, Salmore and Nelson 2000, Norgaard et al. 2013). Therefore, it is recommended these therapies should be offered to patients.

Domain 5: Intra-procedural patient assessment and monitoring

Supplemental oxygen

It is widely recognised, and already recommended in previous clinical guidelines for PSA without an anaesthetist, that supplemental oxygen should be used because it reduces the occurrence of hypoxia secondary to respiratory depression (Rozario et al. 2008, ANZCA 2010, Deitch et al. 2008). Therefore, it is recommended that nurses apply supplemental oxygen to all patients who receive nurse-administered PSA in the CCL.

Pulmonary ventilation and oxygenation

Sedative and analgesic medications can depress respiratory drive, resulting in reduced tidal volume, reduced respiratory rate and periods of apnoea (Malamed 2003). Also, a common side effect of PSA is relaxation and consequent displacement of the pharyngeal musculature leading to partial obstruction of the airway (Odom-Forren and Watson 2005). These side effects can lead to inadequate ventilation and oxygenation if corrective interventions are not applied promptly. Therefore, it is recommended that nurses continuously monitor pulmonary ventilation and oxygenation of sedated patients with pulse oximetry and clinical observation of respiration. In addition, capnography should be used to monitor patients who are more likely to experience respiratory depression. Such patients include those

undergoing defibrillation threshold testing, cardioversion, long electrophysiology-based procedures and also those receiving continuous infusions of sedative and analgesic medications (Waugh et al. 2011).

Cardiovascular function

It is recommended that nurses utilise an ECG to monitor heart rate and rhythm and either invasive or non-invasive blood pressure monitoring during PSA (ANZCA 2010, Gross et al. 2002). Furthermore, while impaired cardiovascular function related to nurse-administered PSA in the CCL is rare, evidence suggests corrective interventions such as intravenous fluid bolus and administration of sedation reversal medications are effective treatments (Geiger et al. 1997, Fox et al. 2007, Natale et al. 1996, Pachulski et al. 2001). As such, it is recommended that nurses promptly report to the proceduralist any indication of compromise in cardiac function.

Goal of procedural sedation and analgesia

In order to facilitate optimal titration of PSA, it is recommended that nurses report any signs of pain, discomfort, anxiety and agitation as well as any unintended depression in level of consciousness to the proceduralist. It is further recommended that sedation scales can be used for standardised monitoring of consciousness during sedation over time (Conway et al. In press).

Monitoring during deep sedation

While moderate sedation is targeted for the majority of procedures, a transient increase in the level of sedation is required for defibrillation threshold testing

(DTT) and cardioversion, as these are particularly painful and distressing aspects of procedures (Timperley et al. 2008). In the survey of nurse-administered PSA practice in Australian and New Zealand CCLs that was conducted as part of this project, it was identified that 20% of CCLs do utilise nurse-administered PSA for defibrillation threshold testing and cardioversion (Conway et al. 2013c). Also, previous research has demonstrated the safety of nurse-administered PSA for DTT and cardioversion (Natale et al. 1996, Manolis et al. 2000, Fox et al. 2007, Lipscomb et al. 1998, Kezerashvili et al. 2008, Sayfo et al. 2012). As such, it is recommended nurse-administered PSA can be used. However, as there is a more pronounced impact on respiratory physiology at the level of deep sedation, it is recommended that capnography should be used (Waugh et al. 2011). In addition, nurses should increase the frequency of their assessment and documentation of the adequacy of cardiac and respiratory function. Any indication of compromise in respiratory or cardiac function should be promptly reported to the proceduralist and corrective interventions implemented immediately.

Staffing

Nurse staffing for procedures differs between CCLs (Conway et al. 2013c). Furthermore, in the previous phases of this project, it was identified that nurses generally deemed that one scout nurse was suitable for diagnostic and interventional coronary and vascular procedures, yet they noted that excluding a sedated patient from their direct vision in order to gather equipment was not optimal during electrophysiology-based procedures. The reason noted was that usually higher doses of PSA medications were used (Conway et al. 2013b). It is

important to note that research has not yet been undertaken to compare the effectiveness of different staffing ratios for nurse-administered PSA in the CCL on either patient outcomes, or on costs. As such, further research is required. Nonetheless, it was recommended by consensus that if nurses-administered PSA is to be used for an electrophysiology-based procedure, two scout nurses should be allocated.

Anaesthetic service support

In phase one, it was identified that, due to the unpredictable nature of the effects of PSA on cardiac and respiratory function, situations arise where the patient requires more specialised care than can be supplied by a registered nurse (Conway et al. 2013b). This finding is supported by a study of PSA during electrophysiology-based procedures, where the investigators found that PSA needed to be converted to a general anaesthetic in 11% of cases (Trentman et al. 2009). Therefore, it is recommended by consensus that each institution should establish a system that facilitates access to support from an anaesthetic service for situations that the nurse deems the patient's needs regarding the administration or monitoring of PSA fall outside their scope of practice, even if this means the procedure must be delayed or abandoned.

Domain 6: Post-procedural patient assessment and monitoring

To prevent post-procedural complications related to PSA, patients require close, specialised monitoring by a nurse either in the procedural area, or in another appropriately staffed recovery unit, for a period of time after the procedure has

finished (Gross et al. 2002, ANZCA 2010). It is recommended that patients remain monitored until they are oriented, are able to move all limbs on command, are able to maintain a normal oxygen saturation level without oxygen supplementation and also until their vital signs have returned to baseline level (Gross et al. 2002, ANZCA 2010). A standardised approach to determining suitability for discharge from the recovery area can be achieved with the use of a validated sedation recovery score (Aldrete and Kroulik 1970).

Conclusion

These guidelines provide an important foundation towards the delivery of safe, consistent and evidence-based nursing care for the many patients who receive sedation in the cardiac catheterisation laboratory setting. The guidelines were developed from evidence in the literature and practising clinicians' opinions, which is the process typically used to develop guidelines in healthcare (NHMRC 1998, Shekelle et al. 1999). To ensure our recommendations were applicable to current clinical practice, we thoroughly reviewed existing literature, and then gathered robust data using several methods: a qualitative study, a quantitative survey of practice, and a modified Delphi study. As such, these guidelines provide important information for CCL nurses to consider in their provision of patient care. Similarly, the recommendations provide highly relevant information for institutions to consider regarding their facilities, equipment and the support that they should make available for nurses.

Of note, recommendations based on consensus should be interpreted with caution (Tricoci et al. 2009) and the clinical usefulness of guidelines should be evaluated (Grimshaw et al. 1995); this has yet to be done. Implementation projects are planned to determine the effectiveness of the guidelines in improving patient and health service outcomes. A further limitation of our guidelines is that only CCL nurses were participants in all studies that informed their development. Yet, they could be used as a foundation for national professional bodies that represent the nurses, cardiologists and anaesthetists that work in CCLs to conduct more extensive multi-disciplinary consultation and set standards for PSA practice, resource requirements, competency, education and training.

References

Aldrete JA & Kroulik D (1970) A postanesthetic recovery score. *Anesthesia and Analgesia* 49, 924-934.

Anzca. (2010) *Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical or Surgical Procedures* [Online]. Available: http://www.anzca.edu.au/resources/professional-documents/professional-standards/pdfs/PS9.pdf.

Astley C, Chew D, Aylward P, Molloy D & Depasquale C (2008) A randomised study of three different informational aids prior to coronary angiography, measuring patient recall, satisfaction and anxiety. *Heart, Lung & Circulation* 17, 25-32.

Ayanian JZ, Landrum MB, Normand ST, Guadagnoli E & Mcneil BJ (1998) Rating the appropriateness of coronary angiography: Do practicing physicians agree with an expert panel and with each other? *New England Journal of Medicine* 338, 1896-1904.

Beddoes L, Botti M & Duke M (2008) Patients' experiences of cardiology procedures using minimal conscious sedation. *Heart & Lung* 37, 196-204.

Behan M, Haworth P, Hutchinson N, Trivedi U, Laborde J-C & Hildick-Smith D (2008) Percutaneous aortic valve implants under sedation: Our initial experience. *Catheterization and Cardiovascular Interventions* 72, 1012-1015.

Burton J, Harrah J, Germann C & Dillon D (2006) Does end-tidal carbon dioxide monitoring detect respiratory events prior to current sedation monitoring practices? *Acad Emerg Med.* 13, 500-4. Epub 2006 Mar 28.

Conway A, Page K, Rolley JX & Fulbrook P (2013a) Risk factors for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A matched case-control study. *European Journal of Cardiovascular Nursing* 12, 393-399.

Conway A, Page K, Rolley JX & Worrall-Carter L (In press) A review of sedation scales for the cardiac catheter laboratory. *Journal of PeriAnaesthesia Nursing*.

Conway A, Rolley JX, Fulbrook P & Page K (2013b) Issues and challenges associated with nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A qualitative study. *Journal of Clinical Nursing*.

Conway A, Rolley JX, Page K & Fulbrook P (2012) Australian and New Zealand Nurses' Perceptions of Procedural Sedation and Analgesia in the Cardiac Catheterisation Laboratory: A Qualitative Study. *Heart, Lung & Circulation* 21, S6.

Conway A, Rolley JX, Page K & Fulbrook P (2013c) Trends in nurse-administered procedural sedation and analgesia across Australian and New Zealand cardiac catheterisation laboratories: Results of an electronic survey. *Australian Critical Care*.

Conway AW, Page K, Rolley JX & Worrall-Carter L (2011) Nurse-administered procedural

sedation and analgesia in the cardiac catheter laboratory: An integrative review. *International Journal of Nursing Studies* 48, 1012-1023.

Creswell JW & Plano Clark VL (2007) *Designing and conducting mixed methods research / John W. Creswell, Vicki L. Plano Clark,* UK, SAGE Publications.

De Bono J (2012) Propofol: a safe drug for physician-led procedures? *Europace* 14, 303-305.

Deitch K, Chudnofsky CR & Dominici P (2008) The utility of supplemental oxygen during emergency department procedural sedation with propofol: a randomized, controlled trial. *Ann Emerg Med* 52, 1-8.

Fox DJ, Davidson NC, Bennett DH, Clarke B, Garratt CJ, Hall MCS, Zaidi AM, Patterson K & Fitzpatrick AP (2007) Safety and Acceptability of Implantation of Internal Cardioverter-Defibrillators Under Local Anesthetic and Conscious Sedation. *Pacing & Clinical Electrophysiology* 30, 992-997.

Gaitan BD, Trentman TL, Fassett SL, Mueller JT & Altemose GT (2011) Sedation and analgesia in the electrophysiology laboratory: A national survey of electrophysiologists investigating the who, how, and why? *Journal of Cardiovascular and Thoracic Anesthesia* 25, 647-659.

Gallagher R, Trotter R & Donoghue J (2010) Preprocedural concerns and anxiety assessment in patients undergoing coronary angiography and percutaneous coronary interventions. *European Journal of Cardiovascular Nursing* 9, 38-44.

Geiger M, Wase A, Kearney M, Brandon M, Kent V, Newby K & Natale A (1997) Evaluation of the safety and efficacy of deep sedation for electrophysiology procedures administered in the absence of an anesthetist. *Pacing Clin Electrophysiol.* 20, 1808-14.

Grimshaw J, Eccles M & Russell I (1995) Developing clinically valid clinical practice guidelines. *Journal Of Evaluation In Clinical Practice* 1, 37-48.

Gross J, Farmington C, Bailey P, Connis R, Cote C, Davis F, Epstein B, Gilbertson L, Nickinovich D, Zerwas J & Zuccaro G (2002) Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology* 96, 1004-1017.

Hasson F, Keeney S & Mckenna H (2000) Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing* 32, 1008-1015.

Hayman M, Forrest P & Kam P (2012) Anesthesia for interventional cardiology. *Journal of cardiovascular and Thoracic Anesthesia* 26, 134-147.

Hummel JD & Awad H (2011) Walking the tightrope between deep sedation and general anesthesia: By who can this safely be done? *Journal of Cardiovascular Electrophysiology* 22, 1344-1345.

Kezerashvili A, Fisher JD, Delaney J, Mushiyev S, Monahan E, Taylor V, Kim SG, Ferrick KJ, Gross JN, Palma EC, Krumerman AK, Kezerashvili A, Fisher JD, Delaney J, Mushiyev S, Monahan E, Taylor V, Kim SG, Ferrick KJ, Gross JN, Palma EC & Krumerman AK (2008) Intravenous sedation for cardiac procedures can be administered safely and cost-

effectively by non-anesthesia personnel. *Journal of Interventional Cardiac Electrophysiology* 21, 43-51.

Kottkamp H, Hindricks G, Eitel C, Muller K, Siedziako A & Koch J (2011) Deep sedation for catheter ablation of atrial fibrillation: A prospective study in 650 consecutive patients. *Journal of Cardiovascular Electrophysiology* 22, 1339-1343.

Lipscomb K, Linker N & Fitzpatrick A (1998) Subpectoral implantation of a cardioverter defibrillator under local anaesthesia. *Heart.* 79, 253-5.

Malamed S (2003) *Sedation a guide to patient management.,* St Louis, Mosby.

Mandel JE, Hutchinson MD & Marchlinski FE (2011) Remifentanil-midazolam sedation provides hemodynamic stability and comfort during epicardial ablation of ventricular tachycardia. *Journal of Cardiovascular Electrophysiology* 22, 464-466.

Manolis A, Maounis T, Vassilikos V, Chiladakis J & Cokkinos D (2000) Electrophysiologist-implanted transvenous cardioverter defibrillators using local versus general anesthesia. *Pacing Clin Electrophysiol.* 23, 96-105.

Mckenna HP (1994) The Delphi technique: a worthwhile approach for nursing? *Journal of Advanced Nursing* 19, 1221-1225.

Natale A, Kearney M, Brandon M, Kent V, Wase A, Newby K, Pisano E & Geiger M (1996) Safety of nurse-administered deep sedation for defibrillator implantation in the electrophysiology laboratory. *J Cardiovasc Electrophysiol.* 7, 301-6.

Nhmrc 1998. A guide to the development, implementation and evaluation of clinical practice guidelines. *In:* AUSTRALIA, C. O. (ed.). Canberra: Commonwealth of Australia.

Nilsson U, Lindell L, Eriksson A & Kellerth T (2009) The effect of music intervention in relation to gender during coronary angiographic procedures: A randomized clinical trial. *European Journal of Cardiovascular Nursing* 8, 200-206.

Norgaard MW, Werner A, Abrahamsen R, Larsen B, Darmer M & Pedersen PU (2013) Visualization and Attentive Behavior for Pain Reduction during Radiofrequency Ablation of Atrial Fibrillation. *Pacing and Clinical Electrophysilogy* 36, 203-213.

Odom-Forren J (2005) The evolution of nurse-monitored sedation. *Journal of Perianaesthesia Nursing* 20, 385-398.

Odom-Forren J & Watson D (2005) *Practical guide to moderate sedation-analgesia 2nd ed.,* St Louis, MO., Elsevier Mosby.

Pachulski R, Adkins D & Mirza H (2001) Conscious sedation with intermittent midazolam and fentanyl in electrophysiology procedures. *J Interv Cardiol.* 14, 143-6.

Pettersen KI, Veenstra M, Guldvog B & Kolstad A (2004) The Patient Experiences Questionnaire: development, validity and reliability. *International Journal for Quality in Health Care* 16, 453-463.

Powell C (2003) The Delphi technique: myths and realities. *Journal of Advanced Nursing* 41, 376-382.

Qadeer MA, Rocio Lopez A, Dumot JA & Vargo JJ (2009) Risk factors for hypoxemia during ambulatory gastrointestinal endoscopy in ASA I-II patients. *Digestive Diseases And Sciences* 54, 1035-1040.

Rolley JX, Salamonson Y, Dennison CR & Davidson PM (2011) Development of clinical practice guidelines for the nursing care of people undergoing percutaneous coronary interventions: An Australian & New Zealand collaboration. *Australian Critical Care* 23, 177-187.

Rozario L, Sloper D & Sheridan M (2008) Supplemental oxygen during moderate sedation and the occurrence of clinically significant desaturation during endoscopic procedures. *Gastroenterol Nurs.* 31, 281-5.

Salmore RG & Nelson JP (2000) The effect of preprocedure teaching, relaxation instruction, and music on anxiety as measured by blood pressures in an outpatient gastrointestinal endoscopy laboratory. *Gastroenterology Nursing* 23, 102-110.

Salukhe T, Willems S, Drewitz I, Steven D, Hoffman B & Heitmann K (2012) Propofol sedation administered by cardiologists without assisted ventilation for long cardiac interventions: an assessment of 1000 consecutive patients undergoing atrial fibrillation ablation. *Europace* 14, 325-330.

Sayfo S, Vakil KP, Alqaqa'a A, Flippin H, Bhakta D, Yadav AV, Miller JM & Groh WJ (2012) A retrospective analysis of proceduralist-directed, nurse-administered propofol sedation for implantable cardioverter-defibrillator procedures. *Heart Rhythm* 9, 342-346.

Shekelle PG, Woolf SH, Eccles M & Grimshaw J (1999) Clinical guidelines: Developing guidelines. *British Medical Journal* 318, 593-596.

Tang R, Dong JZ, Zhao WD, Liu XP, Kang JP & Long DY (2007) Unconscious sedation with propofol versus conscious sedation with fentanyl/midazolam for catheter ablation of atrial fibrillation ablation: A prospective, randomised study. *Chinese Medicine Journal* 120, 2036-2038.

Taylor D, Bell A, Holdgate A, Macbean C, Huynh T, Thom O, Augello M, Millar R, Day R, Williams A, Ritchie P & Pasco J (2011) Risk factors for sedation-related events during procedural sedation and analgesia in the emergency department. *Emergency Medicine Australia* 23, 466-473.

Timperley J, Leeson P, Mitchell A & Betts T (2008) *Pacemakers and ICDs,* Oxford, Oxford University Press.

Trentman TL, Fassett SL, Mueller JT, Altemose GT, Trentman TL, Fassett SL, Mueller JT & Altemose GT (2009) Airway interventions in the cardiac electrophysiology laboratory: a retrospective review. *Journal of Cardiothoracic & Vascular Anesthesia* 23, 841-5.

Tricoci P, Allen JM, Kramer JM, Califf RM & Smith SC, Jr (2009) Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines. *JAMA* 301, 831-841.

Vella K, Goldfrad C, Rowan K, Bion J & Black N (2000) Use of consensus development to

establish national research priorities in critical care. *British Medical Journal* 320, 976-980.

Waugh JB, Epps CA & Khodneva YA (2011) Capnography enhances surveillance of respiratory events during procedural sedation: a meta-analysis. *Journal of Clinical Anesthesia* 23, 189-196.

Woodhead J, Harding S, Simmonds M, Dee S & Mcbride-Henry K (2007) Premedication for Cardiac Catheterization and Percutaneous Coronary Intervention: Does It Increase Vascular Access Site Complications? *Journal of Cardiovascular Nursing November/December* 22, 466-471.

Wright R & Stein M (2005) Snowball sampling. *Encycopedia of Social Measurement.*

Wutzler A, Rolf S, Huemer M, Parwani A, Boldt L, Herberger E, Hohenbichler K, Deitz R & Haverkamp W (2012) Safety aspects of deep sedation during catheter ablation of atrial fibrillation. *Pacing and Clinical Electrophysilogy* 35, 38-43.

Table 1 Recommendation Assessment Items

Item	Response Type
I agree with this recommendation	10-point scale
I agree with the grade of this recommendation	10-point scale
I agree with the level of evidence for this recommendation	10-point scale
This recommendation is relevant to interventional cardiovascular nursing practice	10-point scale
Is this recommendation already adopted within your practice setting?	Yes/No
This recommendation could easily be adopted within my practice setting	10-point scale
If you disagree with the wording of this recommendation, please provide an alternative.	Free text

Table 2 Grading system for evidence and recommendations (Rolley et al. 2011)

Level of evidence	Study design	Grade of recommendation	Description
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.	A	Body of evidence can be trusted to guide practice.
II	Evidence obtained from at least one properly designed randomised controlled trial.	B	Body of evidence can be trusted to guide practice in most circumstances.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).	C	Body of evidence provides some support for recommendations but care should be taken in application.
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case—control studies, or interrupted time series with a control group.	D	Evidence is weak and recommendation should be applied with caution. Consensus based on expert opinion only.
III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.		
IV	Evidence obtained from case series, either post-test or pre-test and post-test.		

Table 3 Summary of guideline statements

Recommendation	Median score	Grade of recommendation	Level of Evidence
Domain 1: Pre-procedural assessment			
For patients scheduled to receive deep sedation without an anaesthetist present (electrophysiology procedures during which continuous infusions of sedative or analgesic medications are to be administered, DTT or cardioversion)	9	D	-
Alert the Cardiologist if: • BMI > 35 • Prior difficulty with sedation/anaesthesia • Substance abuse • Expected length of procedure > 6 hours • Sleep apnoea, undiagnosed but high-risk for sleep apnoea (assessed using Berlin questionnaire) or obesity hypoventilation syndrome (assessed using serum venous bicarbonate) • Significant respiratory disease, SpO_2 < 94% on room air • Significant renal/hepatic impairment • Low ejection fraction			
Consider the potential for extended duration of sedation recovery in order to facilitate adequate post-procedural staffing ratios.	8	D	-

Consider risk factors of impaired respiratory function in order to tailor appropriate strategies for intensive respiratory monitoring. • Emergency admission • Transfer from a critical care unit (intensive care unit, coronary care unit, emergency department) • On haemodynamic support in lead up to the procedure (temporary pacing, inotropes, anti-arrhythmics, vasodilators) • On respiratory support in lead up to the procedure (supplemental oxygen) • Potential requirement for deep sedation during defibrillation threshold testing or cardioversion	8	C	III-2
Consider risk factors of increased pain and discomfort • Previous muscloskeletal injuries • High levels of anxiety (Faces Anxiety Scale is a simple tool that can be used to identify high levels of anxiety)	8	C	IV
Domain 2: Pre-procedural patient and family education			
Information should be made available to patients and their families, which clearly outlines the proposed method of sedation and analgesia. If the proposed method is nurse-administered procedural sedation and analgesia rather than a general anaesthetic, a clear description of the anticipated degree of pain and discomfort associated with the procedure should be provided and consent signifying the patient's understanding and willingness to undergo the procedure with this mode of sedation.	8	D	-

Domain 3: Pre-procedural patient comfort			
The use of pre-procedural sedation with oral medications should be administered on a patient-specific basis only .	9	B	II
Domain 4: Intra-procedural patient comfort			
The proceduralist may prescribe a combination of benzodiazepines and opioids for a registered nurse to administer intravenously, either pre-emptively for procedures known to induce a considerable degree of pain and discomfort, or in response to either patient self-report, or clinical signs of anxiety, pain and discomfort associated with the procedure.	10	B	IV
The proceduralist must be present when sedation is administered by the registered nurse.			
Other sedative and analgesic agents, such as propofol, dexmedetomidine, ketamine and remifentanil, have several desirable properties over the opioid and benzodiazepine combination that is most commonly used for PSA including rapid onset of action and short half-life. Also, evidence demonstrating their safety is emerging. However, more evidence is required in order to explicate the type of patients that are suitable, the degree of patient monitoring that is required and specific education, training and accreditation requirements. Therefore, the use of these agents for nurse-administered sedation in the CCL is not recommended.	10	C	IV
Non-pharmacological stress reducing therapies, such as music and visualisation, should be offered for patients who choose to utilise this relaxation technique to reduce anxiety during procedures in the CCL.	8	B	II
Domain 5: Intra-procedural patient assessment and monitoring			
Administer supplemental oxygen to patients who receive intravenous sedative and analgesic	9	B	II

medications.			
If sedation and analgesia is administered, nurses should continuously monitor pulmonary ventilation and oxygenation using pulse oximetry combined with clinical observation of respiration in order to detect potential complications including: -Hypopnoeic hyopventilation (reduced tidal volume) -Bradypnoea (reduced respiratory rate) -Apnoea (absence of respiration) -Partial airway obstruction Adequacy of ventilation and oxygenation should be recorded before and after sedative and analgesic titration and at least every 10 minutes by documenting the oxygen saturation value and respiratory rate. Any indication of respiratory compromise needs to be promptly reported to the proceduralist and corrective interventions implemented immediately. Corrective interventions for impaired respiratory function may include repeated physical stimulation, airway realignment or placement of airway adjuncts, increasing supplemental oxygen or administration of sedation-reversal medications.	10	D	IV

Capnography should be used in addition to pulse oximetry and clinical observation of respiration for all patients at higher risk of impaired respiratory function during procedural sedation and analgesia. Risk factors for impaired respiratory function include: 1. Deep sedation for cardioversion or defibrillation threshold testing. 2. Electrophysiology procedures with prolonged duration. 3. For any procedures during which continuous infusions of sedative or analgesic medications are administered Adequacy of ventilation and oxygenation when capnography is being used should be recorded by documenting the oxygen saturation value, respiratory rate, characteristics of the capnographic waveform and end-tidal carbon dioxide value.	8	D	-
Nurses should monitor cardiovascular function using invasive or non-invasive blood pressure measurement and an ECG to monitor heart rate and rhythm in order to detect potential complications related to sedation including hypotension and bradycardia. Any indication of compromise in cardiac function needs to be promptly reported to the proceduralist and corrective interventions implemented immediately. Corrective interventions for impaired cardiac function related to sedation may include intravenous fluid bolus or administration of sedation-reversal medications. Adequacy of cardiovascular function should be recorded before and after sedative and analgesic titration and at least every 10 minutes by documenting the blood pressure, heart rate and heart rhythm.	9	D	IV
The goal for nurse-administered procedural sedation and analgesia in the CCL should be for the patient to retain the ability to respond to verbal stimulation and maintain normal cardiopulmonary function while providing as much comfort as possible.	9	D	IV

Nurses should report any signs of pain, discomfort, anxiety and agitation to the proceduralist in order to facilitate titration of sedation and analgesia. While patients can self-report feelings of distress, nurses should also monitor for clinical signs of pain, discomfort, anxiety and agitation, as well as the effectiveness of sedation and analgesia in reducing or alleviating these distressing experiences. **Clinical signs of pain/discomfort/anxiety include:** -Increasing heart rate and blood pressure -Frequent readjustment of body position -Facial grimacing -Groaning **Clinical signs of agitation include:** -Uncontrolled leg movements -Reaching for groin or oxygen mask	10	D	-

Nurses should regularly monitor level of consciousness during procedural sedation and analgesia. The level of consciousness should be documented before and after sedative and analgesic titration as well as at least every 10 minutes. Consciousness should be assessed by determining the degree of stimulation required to elicit a PURPOSEFUL response. The stimulation should begin as verbal, then progress to increasing levels of physical stimulation. Careful attention should be focused on distinguishing reflex withdrawal from a 'purposeful' response to stimulation, such as the ability to follow simple commands (e.g. establishing eye contact or responding with comprehensible words). If there is an unintended further depression in the level of consciousness, such that the patient does not respond to verbal stimulation, nurses should first implement a simple corrective intervention, such as repeated physical stimulation. Also, it is essential that the depressed level of consciousness is reported to the proceduralist so that further doses of sedative and analgesic medications can be withheld or infusions of sedative medications can be discontinued until such a time that the patient responds purposefully to verbal stimulation. In the case that the patient remains unresponsive to verbal stimulation, airway adjuncts can be used in order to protect the patient's airway and administration of sedation reversal medications may also be required.	9	D	IV
Scales can be used to assess level of consciousness during sedation (Observer's assessment of alertness/sedation OAA/S).	9	D	-
At the cardiologist's discretion, a purposeful increase in the level of sedation, to the point that the patient does not respond to verbal stimulation, may be used to facilitate defibrillation threshold testing and cardioversion.	8	C	IV

In the case that nurse-administered procedural sedation and analgesia is used for defibrillation threshold testing or cardioversion, nurses should use capnography to monitor ventilation and increase the frequency of their assessment and documentation of the adequacy of cardiac and respiratory function (refer to Domain Four - Recommendations 1-3). Any indication that cardiac or respiratory compromise has occurred should be promptly reported to the proceduralist and corrective interventions implemented immediately. After defibrillation threshold testing or cardioversion, level of consciousness and adequacy of cardiac and respiratory function needs to be monitored continuously until the patient is responsive to verbal stimulation. If the patient remains unresponsive to verbal stimulation, nurses should first implement a simple corrective intervention, such as repeated physical stimulation. Also, it is essential that the prolonged depressed level of consciousness is reported to the proceduralist so that further doses of sedative and analgesic medications can be withheld or infusions of sedative medications can be discontinued until such a time that the patient responds purposefully to verbal stimulation. In the case that the patient remains unresponsive to verbal stimulation, airway adjuncts can be used in order to protect the patient's airway and administration of sedation-reversal medications may be required.	8	D	-
For diagnostic and interventional coronary and vascular procedures, the registered nurse can be responsible for duties other than sedation administration and monitoring provided there is another registered nurse or cardiac technician/physiologist allocated to the procedure who is performing the advanced cardiac monitoring role.	8	D	-

For electrophysiology procedures (including pacing, ICD, CRT, EPS, Ablation), renal denervation procedures and structural heart procedures during which nurse-administered procedural sedation and analgesia is intended to be used, two registered nurses need to be allocated to the case. The primary duty of at least one of the registered nurses is to administer and monitor sedation and implement any interventions required to support or restore respiratory or cardiac function, while the other can be responsible for other duties.	8	D	-
Systems should be in place so that if at any time before or during the procedure the nurse considers the patient's procedural sedation and analgesia requirements to fall outside of their scope of practice, support from an anaesthetist must be arranged, even if this means the procedure must be delayed or abandoned.	10	D	-
Domain 6: Post-procedural patient assessment and monitoring			
Patients who receive nurse-administered procedural sedation and analgesia are to remain in the procedural area or another clinical area where close, specialised monitoring of the patient's sedation status can be provided until the patient is oriented, able to move all limbs on command, is able to maintain their oxygen saturations without oxygen supplementation and vital signs have either returned to baseline or are within acceptable limits.	10	D	-
A validated standardised assessment tool, such as the Post Anaesthetic Recovery Score (PARS), should be used to document the patient's progress to recovery from sedation at regular intervals and prior to being discharged from the clinical area in which they are being recovered.	9	C	III-1

***** A proceduralist was defined as a physician, usually a specialist or subspecialist who performs diagnostic or therapeutic procedures.

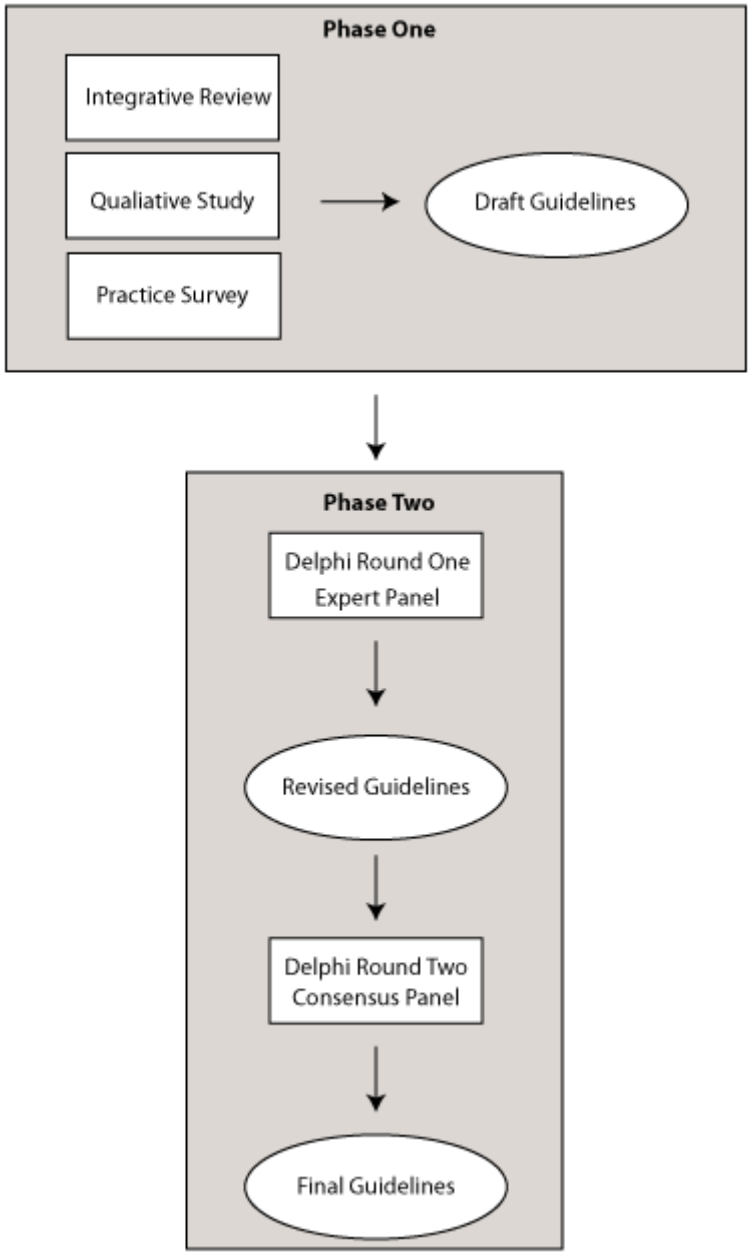

Figure 1 Guideline Development Method